UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

BAUSH & LOMB INCORPORATED & PF CONSUMER HEALTHCARE 1 LLC Plaintiffs, vs. SBH HOLDINGS LLC, Defendant	Civil Action No.: 20-cv-01463-LPS **DEFENDANT'S BRIEF IN SUPPORT OF MOTION TO DISMISS COMPLAINT AND/OR FOR A MORE DEFINITE STATEMENT** RULE 12(B)(6) AND/OR 12(E)

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I. STATEMENT OF MATTER AND STAGE OF PROCEEDINGS

This is defendants' first motion made under Federal Rule of Civil Procedure 12(b)(6) on the grounds that plaintiffs' complaint fails to state a claim upon which relief may be granted or alternatively under Federal Rule of Civil Procedure 12(e) for a more definite statement on the grounds that plaintiffs' complaint fails to adequately apprise defendant of the factual basis for the ostensible claims alleged in the complaint.

This is plaintiffs' second lawsuit against defendant alleging infringement of the same patents, U.S. Patents Nos. 6,660,297 and 8,605,522. Plaintiffs filed their first complaint against defendants in the Western District of New York on June 30, 2020. Plaintiffs waited 71 days before they effectuated service thereof on September10, 2020. That complaint and the subject one in this Court ignore that file history estoppel severely limits the scope of the asserted claims, which estoppel serves to bar any action against defendant. Due to file history estoppel, there is and cannot be any claim for infringement against defendant

Willfully ignoring the Supreme Court's decision in *TC Heartland LLC v. Kraft Food Grp. Brands LLC*, 137 S. Ct. 1514 (2017) that venue in patent cases is governed exclusively by 28 U.S.C. § 1400(b), plaintiffs wrongfully brought their first action in the Western District of New York knowing full well that: (1) the defendant did not reside there and (2) the defendant did not commit acts of infringement *and* did not have regular and established place of business there. Plaintiffs' counsel, although acknowledging the venue as improper, refused to dismiss. Accordingly, defendant filed a motion to dismiss for lack of venue. On the eve of plaintiffs' opposition to the motion to dismiss being due, the plaintiffs filed and served the instant action in this Court, thus maintaining the same action at the same time in two separate district courts. Plaintiffs tried to leverage this second action to force defendant to acquiesce to venue in the Western District. Defendant rejected this abuse of process and plaintiffs dismissed the Western District action.

Promptly upon notice of the instant action, defendant's counsel, as it had in the Western District action, again advised plaintiffs that due to file history estoppel the subject patent claims did not read on defendant's products or activities. Defendant sought a claims chart from plaintiffs to support their claims of infringement. Tellingly, none was forthcoming. Thus, defendants are filing the subject motions.

Local Rule 7.1.1 Statement; Defendant's local counsel has orally met and conferred with plaintiffs' local counsel per Local Rule 7.1.1 and the undersigned avers he undertook a reasonable effort to reach resolution of these motions with local plaintiffs' counsel

II. SUMMARY OF ARGUMENT

First, the complaint does not meet the pleading standards required to assert a patent infringement claim. In *Golden v. Apple Inc*., No, 2020-1508 (Fed Cir. Sept. 3,2020), (non-precedential opinion) the Federal Circuit summarized the applicable law:

> "Allegations of direct infringement are subject to the pleading standards established by *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009). Under this standard, a court must dismiss a complaint if it fails to allege "enough facts to state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570. This "facial plausibility" standard requires "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Id. at 555. Rather, it requires the plaintiff to allege facts that add up to "more than a sheer possibility that a defendant has acted unlawfully." Iqbal, 556 U.S. at 678; see *Twombly*, 550 U.S. at 555 ("Factual allegations must be enough to raise a right to relief above the speculative level."). Although courts do not require "heightened fact pleading of specifics," *Twombly*, 550 U.S. at 570, a plaintiff must allege "'enough fact[s] to raise a reasonable expectation that discovery will reveal' that the defendant is liable for the misconduct alleged." In re *Bill of Lading Transmission & Processing Sys. Pat. Litig*., 681 F.3d 1323, 1341 (Fed. Cir. 2012) (alteration in original) (quoting *Twombly*, 550 U.S. at 556)".

Here, plaintiffs plead no facts, much less "enough fact[s] to raise a reasonable expectation that discovery will reveal' that the defendant is liable for the misconduct." Thus, it must be dismissed under Federal Rule of Civil Procedure 12(b)(6) on the grounds that plaintiffs' complaint fails to state a claim upon which relief may be granted.

The file histories of the '297 patent and the '522 patent, attached hereto, very plainly show file history estoppel precluding, as a matter of law, a finding of infringement by SBH of any patent claim. Plaintiffs' patent claims, throughout prosecution of the two patent applications leading to the patents in suit, have never varied as to the content of vitamin C (as a daily dosage): 420 to 600 mg (sometimes expressed as 7 to 10 times the RDA, the RDA at the time of the application being 60 mg.). SBH's vitamin C indisputable content (750 mg) is therefore 25% above the maximum vitamin C stated consistently in plaintiffs' patent claims, and 67% higher than the preferred vitamin C content of 450 mg as expressed in some of the claims. As supported below, the patent examiners in the patent applications stated, on allowing the claims, that the allowance was based on the "particular concentrations" of the recited ingredients "to have a synergistic effect on treating macular degeneration." Under the file history estoppel doctrine, the plaintiffs cannot assert a claim for infringement. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co*., 535 U.S. 772 (2002).

Alternatively, the plaintiffs' claims must be pled more definitively because of the file histories of the '297 patent and the '522 patent. The complaint is purposely vague as to how the claim patents read on defendant's product. Plaintiffs, despite repeated request from defendants, refuse to provide a claims chart or other evidence as to how defendant's product can possibly infringe the subject patents, given the patents' prosecution history. The plaintiffs should not be able to burden defendant or this court by hiding behind an obtuse and a vague pleading. Thus, failing outright dismissal of the complaint, plaintiffs should be ordered under Federal Rule of Civil Procedure 12(e) to file a more definite statement on the grounds that plaintiffs' complaint fails adequately to apprise defendant of the factual basis for the ostensible claims alleged in the complaint.

III. FACTUAL BACKGROUND

A. Patent Prosecution Background Demonstrating File History Estoppel

Plaintiffs allege infringement of U.S. Patents Nos. 6,660,297 and 8,605,522. In fact, there is no infringement. The complaint ignores that file history estoppel severely limits the scope of the asserted claims to a vitamin C component of 600 mg. Defendant's product has a vitamin C component of 750 mg. See Appendices 3-5 hereto and **IV Argument C** below.

B. Patent Prosecution Background of '297 Patent

Attached hereto as Appendix 1, is the complete file history of the '297 patent prosecution of which judicial notice is requested under Federal Rule of Evidence 201. Defendant has paginated each sheet, hereinafter designated as "FH 297…"

Claim 1 of the '297 patent states (complaint Exhibits A and B, D.I.-1p.7 and D.I.-2 p.3):

> A composition comprising on a daily dosage basis: approximately 7 to 10 times the RDA of vitamin C . . .

Claim 3 of '297 states:

> A method of manufacturing a daily dosage composition comprising: blending not less than approximately 420 mg and not more than approximately 600 mg vitamin C,,,

All claims of the '297 patent include this limitation on vitamin C content. *Id*

Plaintiff repeatedly argued the importance of its specific range of 420 to 600 mg vitamin C, distinguishing that range from higher vitamin C (and sometimes lower vitamin C) in formulas expressed in prior patents and publications.

The '297 patent description confirms the equivalence of 7 to 10 times RDA with 420 to 600 mg; the range cannot "float" over time with changes in RDA. At col. 5, l. 8 - 29, of the '297 patent (D.I.-1 p,5, the specification states that the RDA for vitamin C is 60 mg. The paragraph goes on to state that preferred ranges of approximately 450 mg to 600 mg of vitamin C are "equivalent to approximately 7 to 10 times the RDA." That paragraph also states that the most preferred range for vitamin C is approximately 500 mg to 600 mg vitamin C, and the patent included claims to 450 mg vitamin C.

In the lengthy prosecutions of both of plaintiffs' patent applications, plaintiff repeatedly

argued the criticality of the specific formulas in the claims, including the range of 420 to 600 mg vitamin C. This has never varied. See original claims FH 297 pp. 538-545. In plaintiffs' response to the examiner's rejection early in the prosecution of the '297 patent, the response dated October 15, 2002 (FH 297 pp. 353-357), plaintiff sought to distinguish its formula from the prior Gorsek U.S. Patent No. 6,103,756, ("Gorsek") which described a formula for treating macular degeneration including as essential ingredients, vitamin C, vitamin E, vitamin A and some additional vitamins and minerals. The plaintiff argued, at page 5 (FH 297 p. 354) of that response, that the subject invention "is directed to an unique dietary supplement formulation proven in a ten year study . . ." and "the subject formulation which differs significantly from the teachings of both *Gorsek*'s '756 and D.A. Newsom et al., comprises **6 to 10** times the RDA of vitamin A, **7 to 10** times the RDA of vitamin C, **13 to 18** times the RDA of vitamin E, **4 to 7** times the RDA of zinc and approximately the RDA of copper. ***Gorsek* '756 teaches away from the subject claimed formulation.** *Gorsek*'s '756 teaches a formulation comprising among other essential ingredients . . . 16.7 times the %DV [Daily Value] of vitamin C . . ." [all emphasis in original].

Plaintiff's argument went on to argue that plaintiffs' formula had "approximately **half** the amount of vitamin C" as compared to *Gorsek* (FH 297 p. 5). Further plaintiff then argued "Gorsek '756 teaches away from the importance of the subject five ingredients and the <u>essential formulation amounts</u> disclosed and claimed in the subject application" (FH 297 p. 6) [emphasis added]. At page 7 (FH 297 p. 356) of plaintiffs' response the "unique dietary supplement formulation" was again argued and contrasted from the prior art. And again, with bold-emphasized numbers the argument again set forth the ranges of this "unique formulation", including "**7 to 10** times the RDA of vitamin C".

At page 7-8 of that same response (FH 297 pp. 356 – 357) plaintiff argued distinction from LaHaye Patent No. 5,075,116, ("LaHaye") stating "LaHaye et al., '116 teach away from the importance of the subject five ingredients and the <u>essential formulation amounts</u> disclosed and claimed in the subject invention [emphasis added]."

After the application was finally rejected, plaintiff filed a notice of appeal but did not go

through the appeal process. Instead, plaintiff filed another response and argument May 30, 2003 (FH 297 pp. 83 – 93). Again plaintiff argued, in distinguishing from the prior art which included the *Gorsek* reference: "It is through the unique combination of **6 to 10** times the RDA of vitamin A as beta carotene, **7 to 10** times the RDA of vitamin C, **13 to 18** times the RDA of vitamin E, **4 to 7** times the RDA of zinc and approximately the RDA of copper that the beneficial effects of the present invention are achieved." (FH 297 p. 86) Plaintiff further argued (at FH 297 p. 89), "Since LaHaye states that the seven essential ingredients are synergistic, why would a person of ordinary skill in the art vary the ingredients and their concentrations and still expect to obtain the described synergistic results? [all emphasis original]"

A further response filed June 2, 2003 repeated the arguments distinguishing plaintiffs' formula, including the specific range of 7 to 10 times RDA of vitamin C, as distinguished form the prior art including *Gorsek*.

Further arguments were made in a response filed July 30, 2003 (FH 297 pp. 46 – 54), again including arguments distinguishing the applicant's specific formula, including the vitamin C range, from *Gorsek*, with bold emphasis of the "unique combination" ingredient ranges, including 7 – 10 times RDA of vitamin C. Plaintiff argued "Gorsek does not teach the present invention or the surprising beneficial effects achieved by the specific formulation of vitamin A as beta carotene, vitamin C, vitamin E, zinc and copper . . ." The applicant held a telephone interview with the examiner, and after further arguments, the application was allowed.

The application was allowed on August 26, 2003 (FH 297 pp. 11 – 17). In the notice of allowability the examiner stated his reasons for allowance of the claims. As provided for in 37 CFR 1.104 and §1302.14 of the Manual of Patent Examining Procedure (MPEP), a statement of reasons for allowance is not required but can be made if the examiner believes it will help show why the claims were allowed. As stated in the MPEP:

> One of the primary purposes of 37 CFR 1.104(e) is to improve the quality and reliability of issued patents by providing a complete file history which should clearly reflect, as much as reasonably possible, the reasons why the application was allowed. Such information facilitates evaluation of the scope and strength of a patent by the patentee and the public and may help avoid or simplify litigation

of a patent.

In this case the examiner did include a statement of reasons for allowance, as follows (FH 297 p. 16):

> The following is an examiner's statement of reasons for allowance: The prior art fails to teach or suggest a composition that contains the recited five essential components, vitamins A, C, E, zinc and copper in their recited concentrations on a daily dosage basis wherein the synergism between the five components provides a beneficial effect for treating macular degeneration. The prior art did not show this particular combination in theses [sic] particular concentrations on a daily basis to have a synergistic effect on treating macular degeneration. [Emphasis added]

Plaintiff's repeated emphatic arguments that its formula was unique and specific, with repeated emphasis on the numerical ranges as distinct from the prior art, especially *Gorsek* with 16.7 times RDA of vitamin C, absolutely preclude plaintiff from now stating, in this litigation, that it is entitled to a range of equivalents. Plaintiff cannot maintain that its emphatically-argued vitamin C range of 420 to 600 mg is only an approximation or a "soft" limitation, and reach the defendant's formula that has a vitamin C content of 750 mg. Plaintiff in fact distinguished the prior Gorsek macular degeneration formula on the basis that *Gorsek* included a higher amount of vitamin C, and that plaintiff's "unique" and "specific" formula was entitled to a patent over this close prior art. The examiner even emphasized the allowance was based on the specific recited concentrations.

C. Patent Prosecution Background of '522 Patent

Attached hereto as Appendix 2, is the complete file history of the '522 patent prosecution of which judicial notice is requested under Federal Rule of Evidence 201. Defendant has paginated each sheet, hereinafter designated as "FH 522 p…".

Claim 1 of the '522 patent states (see complaint Ex. C, D.I-3 p. 8.):

> A method for stabilizing visual acuity loss in persons with early age-related

> macular degeneration comprising: administering a daily dosage of not less than approximately 420 mg and not more than approximately 600 mg vitamin C . . .

All claims of the '522 patent include this limitation on vitamin C content, sometimes expressed as 7 to 10 times of RDA of vitamin C. *Id*.

Plaintiffs' Patent No. 8,603,522 (the '522 patent, Exhibit C to plaintiffs' complaint D.I.-3, was a full continuation of the '297 patent, based on precisely the same description. Thus, the ingredient ranges had to be consistent with those described in the specification of the '297 patent, and in fact they were virtually the same. The range for vitamin C was always the same in the '522 patent as in the '297 patent: 420 mg to 600 mg. As a continuation application based on the same specification, and with claims having similar limitations, particularly identical limitations regarding vitamin C content, the '522 patent is subject to the same file history estoppel as set forth above regarding the '297 patent.

The '522 patent had an extremely lengthy prosecution, from January 2005 until November of 2013. In addition, plaintiffs' final argument (May 9, 2013, repeated July 31, 2013, FH 522 pp. 21 – 23 and 29 – 34) in the prosecution of the '522 patent, which was the argument that led to allowance, was that its main claims were amended and now had "language common to composition claims of family related U.S. Patent No. 6,602,297" (FH 522 p. 34). Specifically, plaintiff stated "New method claim 29 [now patent claim 11] is consistent with reexamination composition claim 19", and "New claim 34 [now patent claim 16**]** is consistent with reexamination composition claim 31". *Id*. At this point the '297 patent had been reexamined in an inter partes reexamination (D.I-2)and a reexamination certificate had been issued. *Id*. No claim of the '522 patent application had been allowed prior to that point. See fifth rejection of claims,1/18/13 FH 522, 49-58. Therefore, the file history shows that plaintiffs' amendment of claims and the argument submitted on May 9, 2013 (and July 31, 2013) were the reasons for allowance of the application. The sole argument was that the main claims of the application were made to be consistent with claims of the reexamined '297 patent. Thus, the plaintiff essentially equated the claims with those of the '297 patent or at least stated that the claims were of the same scope as those of the '297 patent, and thus were entitled to allowance.

In fact, the examiner (different examiner from '297 patent) stated his reasons for allowance (FH 522 p. 11):

> The following is an examiner's statement of reasons for allowance: The 35 USC 103 rejection-of-record has been obviated by the Inter Partes Reexam Certificate of U.S. Patent No. 6,660,197 [sic, '297] issued on April 30, 2013.

The examiner thus stated the reexamination certificate was the reason for his allowance of the previously consistently rejected '522 patent claims. He agreed with the applicant (plaintiff) that the claims as amended were consistent with the reexamined and allowed '297 patent.

The scope of the claims of the '522 patent is therefore limited by the file history estoppel in the same manner as the '297 claims. No distinction of method versus composition claims can be made here because the composition claims state ingredient amounts on a "daily dosage basis", which incorporates the taking of such amounts daily.

Prior to that final argument, during prosecution of the '522 patent, close prior art was cited by the examiner. The claims were rejected by the examiner five times. Again plaintiff argued the importance and criticality of its ranges of the various ingredients, vitamins C and E, lutein/zeaxanthine, zinc and copper. In one argument, September 23, 2010 (FH 522 pp. 190 – 196), plaintiff argued distinctions of its ingredients as compared to Riley U.S. Patent No. 5,976,568. The table below was included in the response (FH 522 p. 192):

Table 1

Nutritional Component	**Riley's Claim 1**	**Applicants' Claim 4**
vitamin C	20 mg to 1000 mg	420 mg to 600 mg
vitamin E (α-tocerpherol)	5 mg to 2000 mg (7.5 IU to 3000 IU)	400 IU to 540 IU
lutein/zeaxanthine	0.55 mg to 5.5 mg	0.04 mg to 40 mg
Zinc	5 mg to 30 mg	60 mg to 100 mg
Copper	0 mg to 4 mg	1.6 mg to 2.4 mg

Plaintiff argued distinction of its vitamin C range (420 to 600 mg) from Riley's broad range of 20 mg to 1000 mg, saying "In comparison [to Riley], that same person [of skill in the art] finds relatively narrow concentration ranges of the same nutritional components in Applicants' composition recited" (FH 522 pp. 192 – 193) [emphasis added].

By the repeated arguments of the uniqueness of its formula and the narrow scope of its formula compared to prior art, as well as the specific argument distinguishing its vitamin C range from prior art macular degeneration formulas with higher amounts of vitamin C, plaintiff has necessarily limited its vitamin C range to the literal wording of the claims, 420 to 600 mg, in both patents. Beyond these arguments, both **examiners** confirmed the narrow scope of the claimed ranges when they allowed the claims. Defendant's formula and method of treatment with 750 mg vitamin C is well outside the claimed range for vitamin C.

IV. ARGUMENT

A. The Complaint Also Fails to Plead Facts Sufficient to State a Plausible Claim.

Under Federal Rule of Civil Procedure 12(b)(6), a complaint must be dismissed for failure to state a claim (1) for lack of a cognizable legal claim for relief, or (2) for failure to allege facts sufficient to show plausible entitlement to relief under a cognizable legal theory. *Bell Atl. Corp. v. Twombly*, 550 U.S.544, 555 (2007). A plaintiff must plead "enough facts to state a claim to relief that is plausible on its face" to survive a motion to dismiss. *Id*. 570. However, "threadbare recitals of a cause of action's elements, supported by mere conclusory statements" are insufficient. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Rather, a complaint's allegations "must contain sufficient allegations of underlying facts to give fair notice and to enable the opposing party to defend itself effectively (emphasis added)." *Starr v. Baca*, 652 F.3d 1202, 1216 (9th Cir. 2011). Plausibility requires "more than sheer possibility that a defendant has acted unlawfully." *Iqbal*, 556 U.S. at 687. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged (emphasis added)." *Id.*

The Federal Circuit issued its non-precedential decision in *Golden v. Apple Inc.*, No. 2020-1508 (Fed. Cir. Sep. 3, 2020), finding that the plaintiff failed to state a claim for patent infringement despite identifying the asserted claims and accused products and attaching claim charts. The Federal Circuit explained that "conclusory formulaic recitations of the elements of patent infringement" are not sufficient and the claim charts were also inadequate because they "disingenuously us[ed] the words of the claims to generally describe cryptically identified structures." Here, the complaint does not even attempt to meet the pleading standard found deficient in *Golden v. Apple*. No claim chart or similar means to identify how the patent claims read on defendant's products. In *Golden* (non-precedential) ruled:

> Allegations of direct infringement are subject to the pleading standards established by *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662

> (2009). Under this standard, a court must dismiss a complaint if it fails to allege "enough facts to state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570. This "facial plausibility" standard requires "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Id. at 555. Rather, it requires the plaintiff to allege facts that add up to "more than a sheer possibility that a defendant has acted unlawfully." *Iqbal*, 556 U.S. at 678; see *Twombly*, 550 U.S. at 555 ("Factual allegations must be enough to raise a right to relief above the speculative level."). Although courts do not require "heightened fact pleading of specifics," *Twombly*, 550 U.S. at 570, a plaintiff must allege "'enough fact[s] to raise a reasonable expectation that discovery will reveal' that the defendant is liable for the misconduct alleged." In re *Bill of Lading Transmission & Processing Sys. Pat. Litig.*, 681 F.3d 1323, 1341 (Fed. Cir. 2012) (alteration in original) (quoting *Twombly*, 550 U.S. at 556).

Here, plaintiffs plead no facts much less "enough fact[s] to raise a reasonable expectation that discovery will reveal' that the defendant is liable for the misconduct alleged." Plaintiffs' allegation of infringement of the '297 patent is as follows (complaint paragraph 14): SBH is infringing, inducing infringement of, and/or contributing to the infringement of the '297 Patent by making, using, offering to sell, selling, or importing, within this district or elsewhere in the United States, compositions or methods covered by the '297 Patent and/or by selling, offering for sale and/or importing compositions with instructions for use or promotions that cause and induce the user to infringe the claims in the '297 Patent, and/or by selling, offering to sell or importing components or materials, knowing the same to be especially made or especially adapted for use in an infringement of the '297 Patent.

Plaintiffs make the same allegation of infringement of the '522 patent in complaint paragraph 27. Absolutely nothing in these allegations states what claims are infringed or how defendant infringes them. Indeed, there is not even formulaic recitation of the elements of a cause of action -- only simple conclusions of law. To properly state a claim, the complaint must allege specific facts. See e.g. *M2M Solutions LLC v. Telit Comm'ns PLC*, 2015 WL 4640400 (D. Del. Aug. 5, 2015)., 15.

Given the prosecution histories it is manifestly clear that plaintiffs are estopped under Supreme Court precent, *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co*., 535 U.S. 772 (2002), to claim a vitamin C element in excess of 600 mg. Thus, it is not plausible for plaintiffs to assert a claim of infringement unless it can assert in good faith that the accused products have a vitamin C content of 600 mg or less. Plaintiffs cannot plead such in good faith because defendants' products have a vitamin C content of 750 mg.

B. The Court May Take Judicial Notice of Defendant's Vitamin C Content or Alternatively Consider It Under the Incorporation Doctrine

"Generally, district courts may not consider material outside the pleadings when assessing the sufficiency of a complaint under Rule 12(b)(6) of the Federal Rules of Civil Procedure." *Khoja v. Orexigen Therapeutics, Inc.* , 899 F.3d 988 , 998 (9th Cir. 2018). "There are two exceptions to this rule: the incorporation-by-reference doctrine, and judicial notice under Federal Rule of Evidence 201." *Id*. Defendant hereby asks this Court to consider documents outside the complaint through either judicial notice or under the doctrine of incorporation by reference. Defendant contends the undisputed contents of these documents contradict Plaintiffs' "conclusory allegations." Judicial notice under Rule 201 permits a court to judicially notice an adjudicative fact if it is "not subject to reasonable dispute." Fed. R. Evid. 201(b). A fact is "not subject to reasonable dispute" if it is "generally known," or "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." *Id*. Judicial notice of defendants' attached labels are appropriate. *Benak ex rel. Alliance Premier Growth Fund v. Alliance Capital*, 435 F.3d 396, 401 n.15 (3d Cir. 2006) (quoting Fed. R. Evid. 201(b), *see also Twombly*, supra,550 U.S. 568 n.132).

Unlike rule-established judicial notice, incorporation-by-reference is a judicially created doctrine that treats certain documents as though they are part of the complaint itself. The doctrine prevents plaintiffs from selecting only portions of documents that support their claims, while omitting portions of those very documents that weaken — or doom — their claims. *Parrino v.*

FHP, Inc., 146 F.3d 699, 706 (9th Cir. 1998), *superseded by statute on other grounds as recognized in Abrego Abrego v. Dow Chem. Co.*, 443 F.3d 676, 681-82 (9th Cir. 2006) (observing "the policy concern underlying the rule: Preventing plaintiffs from surviving a Rule 12(b)(6) motion by deliberately omitting references to documents upon which their claims are based"). For example, in *Knievel v. ESPN*, 393 F.3d 1068 (9th Cir. 2005), the incorporation of materials was permitted that the complaint did **not** reference at all. Evel Knievel alleged that ESPN defamed him and his wife on its website by posting a picture of them and another woman with an arguably suggestive caption. *Id.* at 1070. In the complaint, Knievel only referenced the allegedly defamatory photo and caption. *Id.* at 1076. ESPN then submitted the surrounding photos and captions to show a reasonable person would not view the caption at issue as defamatory. *Id.* A defamation claim requires showing that the statement at issue, given its context, "is capable of sustaining a defamatory meaning." *Id.* at 1073.

Here, the complaint expressly references in paragraph 15 "SBH's MacularProtect® AREDS 2 and MacularProtect Complete® AREDS 2 products". Attached as Appendices 3, 4 and 5, as verified by the accompanying declaration of Zac Denning, are the labels to these products (and a third one) which cannot be disputed, showing vitamin C content of 750 mg. The Court under the above authority should take judicial notice of these labels or deem them incorporated by reference.

C. The Complaint is Obtuse and Vague Such That Under Federal Rule of Civil Procedure 12(e) a More Definite Statement Must Be Ordered On the Grounds That Plaintiffs' Complaint Fails Adequately to Apprise Defendant of the Factual Basis For the Ostensible Claims Alleged In the Complaint

Under Federal Rule of Civil Procedure 12(e) a complaint with a more definite statement should be ordered on the grounds that plaintiffs' complaint fails to adequately apprise defendant of the factual basis for the ostensible claims alleged in the complaint. As demonstrated by the patent file histories, there is no colorable basis to the subject complaint. Plaintiffs Bausch & Lomb repeatedly and emphatically argued the criticality of its ranges of

ingredients including vitamin C, and the examiner confirmed the very specific ranges as being the reason for allowance. Defendant is well outside the vitamin C range.

Plaintiffs should not be allowed to hide behind their vague pleadings. They should be order to plead a complaint that apprises how they overcome the file history estoppel that make clear defendant are not infringing the patents.

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V. CONCLUSION

Plaintiffs have not, and cannot state a claim for patent infringement due to clear file history estoppel. Thus, plaintiffs' complaint should be dismissed without leave to amend. Failing dismissal without leave to amend, plaintiffs should be ordered to file a more definite complaint addressing why file history estoppel does bar their claims of infringement against defendant.

Dated: November 19, 2020

Respectfully submitted,

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